

(3) The MAC will not consider any new evidence submitted regarding a change in condition of an enrollee after a coverage determination is made. The MAC will remand a case to the Part D IRE if the MAC determines that the enrollee wishes to have evidence on his or her change in condition after the coverage determination considered.

(b) *Subpoenas*. When it is reasonably necessary for the full presentation of a case, the MAC may, on its own initiative, issue subpoenas requiring an enrollee or Part D plan sponsor to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. The MAC may not issue a subpoena to CMS, or the IRE to compel the production of evidence.

(1) To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality or undue burden, was made before the MAC, the Secretary may review immediately that subpoena or a portion of the subpoena.

(2) Upon notice to the MAC that an enrollee or Part D plan sponsor intends to seek the Secretary review of the subpoena, the MAC must stay all proceedings affected by the subpoena, tolling the time period for the MAC to issue a final action or remand a case in response to a request for review for 15 calendar days or until the Secretary makes a decision with respect to the review request, whichever occurs first.

(3) If the Secretary does not grant review within the time allotted for the stay, the stay is lifted and the subpoena stands.

(c) *Enforcement*. (1) If the MAC determines that an enrollee or other person or entity subject to a subpoena issued under this section has refused to comply with the subpoena, the MAC may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(2) After submitting the enforcement request, the time period for the MAC to issue a final action or remand a case in response to a request for review is stayed for 15 calendar days or until the

Secretary makes a decision with respect to the enforcement request, whichever occurs first.

(3) Any enforcement request by the MAC must consist of a written notice to the Secretary describing in detail the MAC's findings of noncompliance and its specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the enrollee or other person or entity subject to the subpoena.

(4) The MAC must promptly mail a copy of the notice and related documents to the enrollee or other person or entity subject to the subpoena, and to any other affected person.

#### § 423.2124 Oral argument.

An enrollee may request to appear before the MAC to present oral argument.

(a) The MAC grants a request for oral argument if it decides that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone.

(b) The MAC may decide on its own that oral argument is necessary to decide the issues in the case. If the MAC decides to hear oral argument, it informs the enrollee of the time and place of the oral argument at least 10 calendar days before the scheduled date or, in the case of an expedited review, at least 2 calendar days before the scheduled date.

(c) In case of a previously unrepresented enrollee, a newly hired representative may request an extension of time for preparation of the oral argument and the MAC must consider whether the extension is reasonable.

(d) The MAC may also request, but not require, CMS, the IRE, and/or the Part D plan sponsor to appear before it if the MAC determines that it may be helpful in resolving the issues in the case.

(e) The MAC cannot draw any adverse inference if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in the oral argument.

#### § 423.2126 Case remanded by the MAC.

(a) *When the MAC may remand a case to the ALJ*. (1) The MAC may remand a